

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JUNE CHO,

Plaintiff,

v.

DUKE UNIVERSITY and MARILYN
HOCKENBERRY

Defendants.

Case No. 1:18-cv-00288-WO-JLW

DECLARATION OF MARILYN HOCKENBERRY

1. My name is Marilyn Hockenberry. I am over the age of 18 and am competent to make this Declaration which is based on my own personal knowledge and I give this Declaration as part of the lawsuit brought by June Cho ("Dr. Cho").
2. I am currently Professor Emeritus at Duke University and Professor of Pediatrics at Baylor College of Medicine. In my role with Baylor, I have developed a curriculum and am instructing nurses in Africa on how to administer cancer treatment to children. I am the author of three Elsevier published pediatric nursing textbooks for the past 18 years that have been translated to many different languages. I am also employed by Duke University part-time in the role of Institutional Review Board ("IRB") Chair.
3. From 2011 to the present, I have been a member of Duke's IRB. The IRB's mission is to ensure the protection of human research subjects. To that end, all study protocols must be reviewed and approved by the IRB from the outset. Any changes to the protocols along the way must also be submitted and approved prior to implementation. IRBs are not unique to Duke; IRBs exist at other institutions conducting human subject research. Currently there are eleven IRB Chairs at Duke.
4. I have served as the Principal Investigator ("PI"), or Co-Investigator on five (5) R-01 research grants from the National Institutes of Health.
5. From September 2015 through August 2018 I held the position of Duke University School of Nursing Associate Dean for Research ("ADR") which within this role I

also served as the Clinical Research Unit Director for the School of Nursing.

6. At Duke, Clinical Research Units (“CRUs”) are responsible for ensuring research integrity and compliance with all state, federal, and institutional regulations and policies. CRU personnel have direct supervisory authority over research staff. In my role, I supervised Research Practice Managers who are part of the CRU. Research study staff report directly to the Research Practice Managers, not the Principal Investigator or “PI.” This reporting structure is intended to avoid concerns of undue influence by a PI, which may be more likely to occur in a centralized power structure.
7. When I began in my role as Associate Dean for Research and Clinical Research Unit Director, Phyllis Kennel was the Research Practice Manager assigned to Dr. Cho’s study.
8. Prior to joining Duke, Dr. Cho was a faculty member at the University of Alabama at Birmingham (“UAB”). While at UAB, Dr. Cho completed the first year of a five-year National Institutes of Health research grant. Dr. Cho served as the PI on the study. When Dr. Cho joined Duke, the grant transferred to Duke. Dr. Cho remained the PI, but Duke became the holder of the grant with ultimate responsibility for ensuring compliance with all federal regulations applicable to human subject research.
9. Shortly before I officially began my role as ADR, I learned of frustrations related to Dr. Cho’s study. Dr. Cho was anxious for her grant to transfer to Duke, which can be a time consuming process. I sent an email to Dr. Cho on August 20, 2015, seeking to reassure her. A true and correct copy of the email is attached as **Attachment A**. However, Dr. Cho was not the only one experiencing frustration with the process. Ms. Kennel and others relayed difficulties they experienced working with Dr. Cho concerning her indecisiveness finalizing the budget, identifying a laboratory that would agree to preform analysis for her study, and identifying co-investigators to work with her. Ms. Kennel summarized her frustrations in an email to me dated September 3, 2015. A true and correct copy of the email is attached as **Attachment B**.
10. Following the successful transfer of the grant, Ms. Kennel made me aware of concerns about Dr. Cho’s treatment of staff. A former neonatal intensive care unit nurse, Becky Jones, was hired as the Study Coordinator for Dr. Cho. Ms. Jones assisted with enrollment of new study subjects, obtaining samples, obtaining consent and other study-related needs. Ms. Jones reported directly to Ms. Kennel.
11. Ms. Kennel made me aware that Dr. Cho was having difficulties identifying a laboratory willing to work on her study. Additionally, I was copied on correspondence noting that Dr. Cho no longer wished to work with statisticians at

Duke, but rather, preferred to work with the statistician she worked with while at UAB who was now at the University of Texas El Paso. I reminded Dr. Cho that she would need to make sure that proper documentation was in order to allow that to occur. A true and correct copy of the email exchange is attached as **Attachment C**.

12. In mid-November 2016, Dr. Kimberly Fisher informed me that Dr. Cho had reopened active recruitment and enrollment of study subjects at UAB. The Duke IRB approved protocol allowed only for follow up on previously enrolled subjects at UAB, not new enrollment. Dr. Cho had not sought amendment and approval for this action from Duke's IRB, nor had she informed Dr. Fisher who was now the coordinator on her study. Around this same time, I also learned that Dr. Cho had sought to utilize videotapes from another study at UAB to train her staff. Use of these materials would, again, require proper documentation, agreements and IRB approval.
13. After learning of these new developments, I consulted with the Vice Dean for Clinical Research at Duke University who at the time was Dr. Mark Stacy. As Clinical Research Director for the School of Nursing I reported to Dr. Stacy as well as the Dean of the School of Nursing for all nursing research related regulatory and compliance matters. Dr. Stacy suggested that I reach out to Duke's Office of Audit, Risk and Compliance to conduct an audit of the study as a first step. The audit was requested in mid-November 2016. Pending the results of the audit, solicitation of new subjects was placed on hold at both Duke and UAB.
14. After Dr. Cho reopened enrollment at UAB, Dr. Kimberly Fisher who was the Director of the Neonatal-Perinatal Research Unit informed me and the School of Nursing that the NPRU no longer intended to support Dr. Cho's study. Effectively, this meant that Dr. Cho could no longer recruit study subjects at Duke since this would have to be done through the NPRU.
15. In my role as Associate Dean for Research and Clinical Research Unit Director, I was obligated to report the audit and related concerns about Dr. Cho's study to the Duke IRB. Accordingly, I consulted with IRB Executive Director Jody Powers. I was informed that the IRB intended to conduct a full board review of Dr. Cho's study. The IRB requested that we contact UAB to make sure that active enrollment was no longer occurring at that site. A true and correct copy of my correspondence with the IRB reflecting our conversation is attached as **Attachment D**.
16. On or about February 28, 2017, Duke's Office of Audit, Risk & Compliance completed its review of Dr. Cho's study. The audit noted deviations from the approved IRB protocol. Specifically, the report noted "non-IRB-approved study visits were attempted/completed at the subjects' residence" and two saliva samples were obtained prior to receiving documented consent. The audit did not address

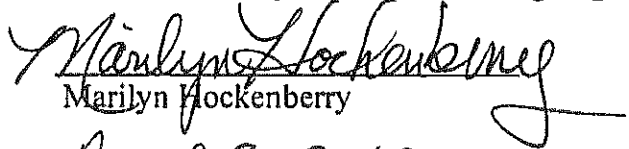
the re-enrollment at UAB and indicated that issue was for the IRB to address.

17. On or about March 22, 2016, Assistant Research Practice Manager Heather Adams came to me with a concern about Dr. Cho's study. By this time, Ms. Kennel had left to take another opportunity with a different Duke entity. Ms. Adams was now the CRU point-person for Dr. Cho's study staff. Ms. Adams told me that she walked into Dr. Cho's office and saw Dr. Cho looking at study information on a computer with a PhD student she intended to hire. Importantly, this hire had not yet been approved. Ms. Adams also informed me, and I confirmed, that Dr. Cho had requested IT grant the student access to folders containing secure electronic data. This should not have been done since the PhD student was not approved on the study. IT complied with Dr. Cho's request as it is not their role to know who is, or is not, on the study. Ms. Adams feared retribution from Dr. Cho, so I agreed to enter the report into the IRB's electronic reporting system. Once I learned of the potential protocol deviation, I was obligated to report it.
18. Once Dr. Cho filed a grievance with the Faculty Ombuds, efforts were undertaken by School of Nursing leadership to keep me out of discussions and/or decisions concerning Dr. Cho.
19. While I am an IRB chair, I was not involved in the full board review of Dr. Cho's study or any discussions regarding the IRB's recommendation that Dr. Cho's PI status be revoked.
20. I was not involved in the discussions regarding the return of Dr. Cho's NIH grant nor the ultimate decision to return the grant.
21. In June 2017, Dr. Turner, Dean Broome, Dr. Fisher, Phyllis Kennel and I attended the Faculty Hearing Committee hearing of Dr. Cho's grievance. The Committee issued its unanimous decision in July 2017 that Dr. Cho was not the subject of impermissible harassment or academic due process violations. Importantly, the Committee's decision noted that Dr. Cho utilized the term "harassment" to refer to alleged "general mistreatment by administration that she found detrimental to her research," not harassment based on national origin or any other protected category. It is my understanding that the Faculty Hearing Committee's decision was upheld at all levels of internal appeal pursued by Dr. Cho.
22. On or about August 2017, I was made aware that Dr. Cho filed a charge with the Equal Employment Opportunity Commission alleging national origin discrimination and retaliation. This was the first time I heard of Dr. Cho raising allegations of national origin discrimination and retaliation. It is my understanding that the EEOC did not find a violation and dismissed the case.

23. I understand that Dr. Cho's complaint alleges that I defamed her. Specifically, she alleges that "on or about April, 2017 Plaintiff's colleagues, including Dr. Im, were warned by Defendant Hockenberry that Plaintiff would become physically dangerous to them when she becomes angry." I did not make this statement. I did not make any similar statement. I did not and do not have concerns about Dr. Cho becoming physically dangerous when she is angry. I was made aware that Dr. Turner had an interaction with Dr. Cho's husband that made her feel uncomfortable and unsafe. I was not present for the interaction.
24. I understand that Dr. Cho contends that I took actions to purposefully cause her harm. I did not. I do not harbor any ill will toward Dr. Cho. I did not and do not have any malice toward her. I did not make any statements or take actions with the intent to cause Dr. Cho harm personally or professionally.
25. My job responsibility was to protect the integrity of Duke University School of Nursing research and seek to ensure compliance with applicable protocols, policies, rules, and regulations. I took this responsibility seriously and reported or escalated concerns regarding Dr. Cho's research study in accordance with this responsibility.
26. I did not and do not harbor any discriminatory animus toward Dr. Cho because of her national origin. I did not take action concerning Dr. Cho because I believed she had raised concerns about national origin discrimination. I did not believe her to have raised any concerns about national origin discrimination until I learned of her EEOC complaint. I do not believe Dr. Cho was discriminated against or retaliated against because of her national origin.

DECLARATION PURSUANT TO 28 U.S.C. § 1746

I declare under penalty of perjury, pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.


Marilyn Hockenberry

Date: April 9, 2019

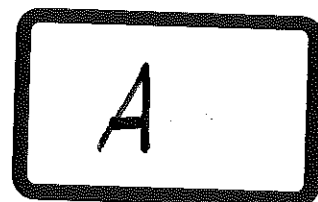
ATTACHMENTS TO THE DECLARATION OF
MARILYN HOCKENBERRY

Phyllis Kennel

From: Marilyn Hockenberry, Ph.D.
Sent: Thursday, August 20, 2015 12:15 PM
To: June Cho
Cc: Phyllis Kennel
Subject: Follow-up

It was nice to meet with you this week to discuss your current RO-1 and future research plans. I look forward to working with you in the future. I have invited you to the mentoring group that I have who meets once a month. I also talked to Phyllis and learned that part of the issue with your study is that the transfer of the grant has not occurred yet- from UAB to Duke. When I came to Duke 3 years ago I had a new RO-1 that I had to transfer and it took me several months to get this in place. Until the monies and grant is officially transferred her your IRB submission will not progress. So take a deep breath, relax and know it will happen.

Best, Marilyn



Phyllis Kennel

From: Jane Halpin
Sent: Thursday, September 03, 2015 9:50 PM
To: Phyllis Kennel
Cc: Robbin Thomas; Marilyn Hockenberry, Ph.D.
Subject: Re: timeline of working with June Cho

Thanks so much for this Phyllis - good summary of the effort we've all undertaken

Sent from my iPhone

On Sep 3, 2015, at 5:17 PM, Phyllis Kennel <phyllis.kennel@dm.duke.edu> wrote:

Hi,
Marilyn has asked me to explain how much time we have spent with June regarding her transfer to Duke. I know some of this is frustrated dribble, but after my conversation with the Dean and Marilyn today it is apparent to me that information isn't being communicated very well about what has been going on. I would like to see if you could correct/add/adjust anything you feel necessary for Marilyn to take this to the Dean.

Thanks!
Phyllis

June Cho started on July 1.

Prior her starting at Duke, Robbin and I met with her several times. We had a conference call with her in March 2015 and then met with her in person twice in May to review her studies, budget and what she was bringing here at that time Jane also got involved. AT the end of May, June was sent a complete list of all the items she needed for the budget resubmission and the documents that she need to prepare and provide to Jane. Robbin and Jane spent a great deal of time working with UAB to get their subcontract which finally arrived the end of July (not sure of time frame).

Through this time, Jane has been working with June to get the documents needed for the submission to NIH and finalize the budget, but complete the budget until the subtract was received from UAB. On several occasions, we spent a great deal of discussion on how she was a no-cost extension and continued to not allow us to finalize the budget. In July she still hadn't finalized samples analysis, co-investigators here at Duke and utilization of the clinic space for data collection. All of this information was shared with Diane as both the ADRA and her mentor.

In the meantime, I wanted to give her assistance to get her IRB ready for submission. I had Angel Barnes work with her to get the documents prepared and put into IRB. As of September 1 she has her CRC III working for her at 15% to help finish up the IRB, and begin study preparations. If for some reason the money didn't go back 90 days to September 1, Diane said she would cover it on the ORA budget.

Two weeks ago, Jane and I met with her to try and finalize the budget. At that time she had an idea of co-investigators and lab but still hadn't had all discussion with the investigators about available

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effort. We were still waiting for several documents needed for the submission such as updated biosketch and facilities information.

Today the Steadman center backed out of doing analysis as well as one of the co-investigators. I worry that Kim Fisher will back out as well for support of her study as she doesn't listen very well and seems to push her agenda very hard. (I was trying to think of a way to say she was stalking Kim Fisher and probably the Steadman Center.

Bottom line, I know the June is providing information to several people (such as the Dean and to you initially) that I don't believe is accurate and making it appear that we aren't supporting her in her efforts to transfer this information. Until you started on Tuesday, were not really getting any support on this issue even after the multiple discussions we had with Diane about the situation.

We have transferred multiple grants over to Duke and one time the program officer from the NIH sent an email to Jane thanking her for her amazing work on the transfer of the grant. (actually it was your grant transfer).

Phyllis Kennel, MS RD LDN
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919-668-5244 (phone); 919-475-9423 (cell)

Office of Research Affairs - BUILDING CAPACITY, MINIMIZING RISK, PROTECTING PEOPLE to improve the lives of patients, their families and communities through meaningful programs of research.

<https://www.youtube.com/watch?v=q3iqBGv3qFg&feature=youtu.be>

Research at DUSON - YouTube

A short video profiling four different research initiatives at DUSON.

Watch now...

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Phyllis Kennel

From: June Cho
Sent: Friday, June 03, 2016 9:10 AM
To: Marilyn Hockenberry, Ph.D.; Barbara Turner, PhD; Wei Pan
Cc: Samuel Morgan; Phyllis Kennel
Subject: RE: Statistical Support for Your R01

Good morning Dr. Hockenberry,

Thank you for the advice. I will work with Sam and Phyllis to make sure everything will be OK.

June

From: Marilyn Hockenberry, Ph.D.
Sent: Friday, June 03, 2016 8:49 AM
To: June Cho; Barbara Turner, PhD; Wei Pan
Cc: Samuel Morgan; Phyllis Kennel
Subject: Re: Statistical Support for Your R01

Please make sure you talk to Phyllis as well. Even though you have published with this individual, since he is outside Duke you will have to address the type of data you will be sending this individual and what needs to be completed before sending. Also if you plan to send specimens to UNC you will also need to make sure an agreement is in place and IRB approves before that occurs.

Thanks! Marilyn

From: June Cho <june.cho@duke.edu>
Date: Thursday, June 2, 2016 8:43 PM
To: "marilyn.hockenberry@duke.edu" <marilyn.hockenberry@duke.edu>, "Barbara Turner, PhD" <barbara.turner@duke.edu>, Wei Pan <wei.pan@duke.edu>
Cc: Samuel Morgan <samuel.morgan@duke.edu>, Phyllis Kennel <phyllis.kennel@duke.edu>
Subject: Re: Statistical Support for Your R01

Dear Dr. Hockenberry:

This statistician you are referring to, Dr. Xu, is not merely a service provider. As you can see from my original R01 grant and the list of my publications, Dr. Xu has been a collaborator for many years in the past. As such, I'd like to keep him as a consultant in my grant, which was what I did when I was at UAB. Tomorrow, I will sit down with Sam to explore this route. Thank you. p/s FYI, Dr. Holditch-Davis also served as a consultant for two NIH grants when I was at UAB.

Sam --- Could you please tell me when you will be available tomorrow? I have a project meeting at 2-3pm.

June



From: Marilyn Hockenberry, Ph.D.
Sent: Thursday, June 2, 2016 7:33:23 PM
To: Barbara Turner, PhD; Wei Pan
Cc: June Cho; Samuel Morgan; Phyllis Kennel
Subject: Re: Statistical Support for Your R01

Please note that since this is an outside person you will need to go through the processes of hiring this individual through a subcontract. Also there will need to be an IRB amendment and DTA established for this person to be able to receive data from you. I am cc'ing Sam Morgan on this and Phyllis to keep everyone in the loop.

From: "Barbara Turner, PhD" <barbara.turner@duke.edu>
Date: Thursday, June 2, 2016 7:04 PM
To: Wei Pan <wei.pan@duke.edu>
Cc: June Cho <june.cho@duke.edu>, "marilyn.hockenberry@duke.edu" <marilyn.hockenberry@duke.edu>
Subject: Re: Statistical Support for Your R01

Dr Pan

Thank you for this quick decision so that Dr Cho does not lose momentum. Dr Cho please move forward with contacting and arranging for the statistical support you need outside of Duke resources. Having your former statistician is a good move and I am appreciative of the center's willingness to accommodate your preference. Thanks to Dr Yang and Dr Chang for the time and energy they put forth on your project. Barb

Barbara S Turner PhD RN FAAN
Elizabeth P Hanes Professor
Chair, Division of Health for Women, Children and Families
Director, Doctor of Nursing Practice Program
Director, Population Care Coordination Program
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email, barbara.turner@duke.edu

DNP project from Africa <https://www.youtube.com/watch?v=6KvqSFgaUqW>

Sent from my iPad please excuse inappropriate autocorrects

On Jun 2, 2016, at 6:13 PM, Wei Pan <wei.pan@duke.edu> wrote:

Dear Dr. Cho,

In the meeting on Tuesday, 5/31/16 (you, Dr. Barb Turner, Dr. Qing Yang, and me), you expressed your intention to change the current statisticians (Dr. Qing Yang and Dr. Jianhong Chang) on your R01 to someone outside Duke. After speaking to my supervisor, we decided that you may do so. So, from now on, we do not have any responsibility to provide statistical support for your project. Hope you will find an outside statistician soon.

Take care,
Wei Pan

Wei Pan, PhD

Associate Professor and Director
Research Design and Statistics Core
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Durham, NC 27710
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wei.pan@duke.edu

Phyllis Kennel

From: Marilyn Hockenberry, Ph.D.
Sent: Thursday, December 08, 2016 9:54 AM
To: Jody Power
Cc: Geeta Swamy, M.D.; Marion Broome, Ph.D.; Phyllis Kennel; Barbara Turner, PhD
Subject: Follow up on Pro00065480

Jody,

Thank you for taking the time to talk to me about the Audit that is currently taking place for Dr. June Cho's research study (Pro00065480). As per your request I am sending you this email notification that there is a formal audit by the Office of Compliance, Audit and Risk taking place on the study this week. The PI opened up a second site at the University of Alabama (where she previously worked) without the Duke IRB's knowledge and we have submitted this to the eIRB and have placed this site opening on hold for now. She has been recruiting at Duke within the Neonatal Research Unit (NRU) and this week the research team involved with Dr. Cho's study notified me that they no longer want to be involved in her research. This includes not only new patient accrual but also the follow-up of existing subjects. I have asked our Research Practice Manager for the Nursing CRU and for Dr. Kim Fisher, Operations Director for the NRU, who also serves as the Regulatory Coordinator for Dr. Cho's study to meet with her and let her know that the Duke site will be closing. I understand that you will be taking this to full board. The auditors feel the final report may take a month to complete. During this time the Nursing CRU plans to keep the UAB site on hold except for data collection on existing subjects. Please advise if there is anything further we need to do.

Marilyn Hockenberry PhD, RN-PPCNP-BC, FAAN
Associate Dean for Research Affairs
Bessie Baker Professor Nursing
Duke School of Nursing
Professor of Pediatrics
IRB Chair
Duke University

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